Amendments to the Drawings:

The attached drawing sheet includes a new Figure 4D, which is to be added to the drawings originally filed with the application. Fig. 4D illustrates the threaded coupling shown in Fig. 4B in greater detail, and as described in paragraph [0048] of the original specification.

Attachment: New Sheet

Remarks/Arguments

In the specification, the disclosure has been amended to correct the informalities identified in the Office Action. Further, a paragraph has been added to the brief description of the drawings to describe new FIG. 4D, and paragraph [0048] has been amended to include a reference to new Fig. 4D.

The attached drawing includes a new Fig. 4D to be added to the drawings originally filed with the application. Fig. 4D is a close-up view of a portion of Fig. 4B and corresponds to subject matter in paragraph [0048] of the description of the embodiment of the invention. Because the content of the drawings is expressly described in the application as filed, applicants respectfully submit that no new matter is added to the application by the additional of Fig. 4D.

Claims 1-14, 16-19, 23, 24, 26, 27, 30-37, 39-42, 44-58, 62, 63, 66, 67, 69 and 70 are currently pending in the application. Claims 15, 20-22, 25, 28-29, 38, 59-61, 64, 65 and 68 are withdrawn. Claim 43 has previously been canceled. By the present amendment, claims 4, 6, 16, 24, 25, 27, 32, 33, 42, 45, 67 and 68 are amended, and new claim 71 has been added. Claim 71 incorporates the subject matter removed from amended claim 4.

Applicants believe the amendments made herein add no new matter. Any amendments to the claims which have been made in this amendment, and which have not been specifically noted to overcome a rejection based on prior art, should be considered to have been made for a purpose unrelated to patentability, and no estoppel should be deemed to be attached thereto. Reconsideration and reexamination of the application is respectfully requested in view of the amendments and the following remarks.

Interview Summary

The Applicants kindly thank the Examiner for the telephonic interview with the Applicants' representative on January 26, 2007. During the interview, the Applicants' representative and the Examiner discussed claims 1-70 in view of the Applicants' response to the requirement for election of species, filed on January 8, 20007. During the

interview, the Applicant's representative confirmed election of claims 1-14, 16-19, 23, 24, 26, 27, 30-37, 39-42, 44-58, 62, 63, 66, 67, 69 and 70 without traverse.

Objections to the Drawings

The drawing are objected to by the Examiner under 37 CFR 1.83(a) for failing to adequately show the threaded coupling of the imaging and guide elements. It is the Examiner's position that element 64 of Figure 4B shows insufficient detail of this feature. Accordingly, applicants have added new Figure 4D, which shows the details of the threaded coupling 64, as described in the specification. Applicants submit that the amendments to the drawings overcome the Examiner's objection.

Objections to the Specification

The disclosure is objected to by the Examiner for informalities detailed in the Office Action. Accordingly, paragraphs [0005], [0019], [0020] and [0036] have been amended in accordance with the Examiner's suggestions. Applicants submit that the amendments overcome the objection.

Objections to the Claims

Claim 4 is objected to by the Examiner under 37 CFR 1.75(c) as failing to further limit the subject matter of the previous claim. Specifically, the Examiner objects to the use of "bioabsorbable or non-bioabsorbable" to describe a portion of the imaging element, stating that this recitation encompasses any and all materials. Claim 4 has been amended to recite only "bioabsorbable" to describe a portion of the imaging element. Applicant's submit that the amendment overcomes the objection with respect to claim 4.

Claim 16 is objected to by the Examiner under 37 CFR 1.75(c) as being of improper dependent form. Claim 16 has been amended to depend from claim 14. Applicant's submit that the amendment overcomes the objection with respect to claim 16.

Claim 23 is objected to for reciting an element with insufficient antecedent basis. However, the term "the imaging device" objected to by the Examiner is not found in claim 23. Applicant's respectfully request that the Examiner's objection with respect to

claim 23 be withdrawn. The term "the imaging device" does appear in claim 24, and therefore Applicants will address this objection with respect to claim 24. Claim 24 had been amended to replace the term "the imaging device" with the term "the imaging element", which has sufficient antecedent basis. Applicant's submit that the amendment overcomes the potential objection with respect to claim 24.

Claim 27 is objected to because it recites an element with insufficient antecedent basis. Claim 27 has been amended to depend from claim 26, which provides sufficient antecedent basis for the element. Applicant's submit that the amendment overcomes the objection with respect to claim 27.

Claim Rejections – 35 U.S.C. § 112

Claim 42 stands rejection under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The rejection is respectfully traversed.

As amended, claim 42 is dependent from claim 30, and further requires the method to comprise the step of locating the area of interest in the tissue mass for surgical excision by following the guide element to the imaging element. A similar step is described in paragraph [0008] of the application as filed, which provides that a localizing wire is typically inserted into a lesion in a tissue mass, using marker which has previously been placed at the lesion to guide the insertion of the localizing wire. The surgeon then follows the localizing wire to the lesion. Applicants' submit that at least the description of the related art provides sufficient detail to apprise one of ordinary skill in the art of how to perform the step of claim 42. Therefore claim 42 meets the enablement requirement and is patentable.

Claim 45 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the suction matter which applicant regards as the invention. The rejection is respectfully traversed.

More particularly, the rejection is based on the use of the terms "easily" and "conveniently" in claim 45 as being relative terms which render the claim indefinite. Applicants' have removed the terms "easily" and "conveniently" from claim 45. Applicants believe these amendments place claim 45 in condition for allowance.

Claim Rejections – 35 U.S.C. § 102

Claims 1-14, 16-19, 23, 24, 26, 27, 30-37, 39-42, 44-58, 62, 63, 66, 67, 69 and 70 stand rejected under 35 U.S.C 102(e) as being anticipated by U.S. Patent Application Publication No. 2005/0165305 to Foerster et al. ("Foerster '305"). The rejection is respectfully traversed.

For Foerster '305 to anticipate these claims, each and every limitation in the claims must by found in Foerster '305. Since such is not the case, the anticipation rejection must fail.

Foerster '305 discloses a marking instrument (10) comprising a marker element (12) having a center wire (18) with a pull ring (24) attached to the proximal end of the center wire (18). The marking instrument (10) further includes a tube (54) having a lumen (56), and the center wire (18) runs through the lumen (56) of the tube (54) with the pull ring (24) positioned proximally of the tube (54). In use, the tube (54) is inserted into a tissue mass and tension is applied to the center wire (18) using the pull ring (24) to bring the marker element (12) into contact with the end of the tube (54) and break the center wire (18) at a point of weakness (72). A proximal portion (18') of the center wire (18) is severed from the marker element (12), while a distal portion (18") remains with the marker element (12). The distal portion (18") is located completely within the tissue mass. A biopsy instrument (26) can be used to place the market element (12) at a desired location within the tissue mass. Foerster '305 also discloses another marking instrument (10b) comprising a marker element (12b) without a center wire that is deployed by pushing the marker (12b) out of a tube (54b) using a mandrel (98).

Claim 1 as amended requires a medical device to comprise an imaging element and a guide element connected to the imaging element and having a separable portion. When the imaging element is placed within a tissue mass, the imaging element is connected to the guide element and at least part of the guide element extends exteriorly of the tissue mass to permit locating an area of interest in the tissue mass. After placement, when the separable portion is separated from the guide element, no part of the guide element extends exteriorly of the tissue mass.

Foerster '305 does not disclose a guide element connected to an imaging element, where the guide element extends exteriorly of the tissue mass when the imaging element is placed. The deployment mechanism taught by Foerster '305 requires that the marker element (12) be brought into contact with the end of the tube (54), causing the marker element (12) to be anchored in the tissue mass and the center wire (18) to break from the marker element (12). Since deployment using the Foerster '305 marking instrument relies on tension to anchor the marker element (12) and to break the connection between the marker element (12) and the center wire (18), it is necessary for the center wire (18) to be withdrawn in order to place the marker element (12). While a distal portion (18") of the center wire (18) may stay with the marker element (12) after it has been placed, this portion (18") is not shown not to extend exteriorly of the tissue mass and does not permit locating the areas of the interest in the tissue mass. In summary, the placement of the marker element (12) of Foerster '305 requires the removal of the center wire (18), resulting in the center wire not being connected to the guide element after placement and no portion of the guide element extending exteriorly of the tissue mass after placement, which are required by claim 1. Therefore, Foerster '305 does not anticipate claim 1 and claim 1 is patentable over Foerster '305. Claims 2-14, 16-19, 23, 24, 26, 27 and 71 are also patentable over Foerster '305 for at least the same reasons that claim 1 is patentable, based on their direct or indirect dependency on claim 1.

Claim 17 is directly dependent on claim 1 and further requires a holder mounted to a portion of the guide element exterior of the tissue mass to hold the position of the guide element relative to the tissue mass.

Foerster '305 does not disclose a holder mounted to a portion of a guide element. The claimed holder is not equivalent to a cannula, as stated by the Examiner. The cannula described by Foerster '305 is used as a delivery apparatus for the marker element (12); as such, the marker element (12) and the center wire (18) are contained within the cannula prior to deployment. The cannula is not mounted to a portion of a guide element, as required by claim 17. Therefore, Foerster '305 does not anticipate claim 17 and claim 17 is patentable over Foerster '305.

Claim 19 is indirectly dependent on claim 1 and further requires a threaded coupling between the guide element and the imaging element to form a releasable connection between the two.

Foerster '305 does not disclose a threaded coupling between a guide element and an imaging element. The Office Action takes the position that a threaded coupling is shown in FIG. 10 of Foerster '305. FIG. 10 shows the marker element (12a) inserted through a loop at the end of the center wire (18a). This is not equivalent to a threaded coupling, as Applicants have applied the term. Applicants have applied the term to mean a connection having screw threads, specifically, cooperating male and female threads (¶ [0048]). Therefore, Foerster '305 does not anticipate claim 19 and claim 19 is patentable over Foerster '305.

Claim 24 is directly dependent on claim 1 and further requires that the imaging element be releasable to permit the repositioning of the imaging element in the tissue mass.

Foerster '305 does not disclose an imaging element that can be repositioned. Foerster '305 makes no provisions for releasing and repositioning the marker element (12) once it is placed in the tissue mass. In fact, in one embodiment of Foerster '305, implantation of the marker element (12) is explicitly stated to be permanent (¶ [0048]). Therefore, Foerster '305 does not anticipate claim 24 and claim 24 is patentable over Foerster '305.

Claim 30 requires a method for localizing and marking an area of interest in a tissue mass to comprise the steps of providing a medical device comprising an imaging element and a guide element connected to the imaging element and inserting the medical device into the tissue mass so that at least part of the guide element extends exteriorly of the tissue mass.

Foerster '305 does not disclose inserting the medical device into a tissue mass so that at least part of a guide element connected to the imaging element extends exteriorly of the tissue mass. The method taught by Foerster '305 relies on tension to break the connection between the market element (12) and the center wire (18) as well as to anchor the marker (12) in the tissue mass, thus requiring that the center wire (18) be withdrawn

in order to place the marker. While a distal portion (18") of the center wire (18) may stay with the marker element (12) after it has been placed, this portion (18") is not said to extend exteriorly of the tissue mass. Therefore, Foerster '305 does not anticipate claim 30 and claim 30 is patentable over Foerster '305. Claims 31-37 and 39-42 are also patentable over Foerster '305 for at least the same reasons that claim 30 is patentable, based on their direct or indirect dependency on claim 30.

Claim 32 is indirectly dependent on claim 30 and further requires the step of unthreading at least a portion of the guide element to remove at a portion of the guide element.

Foerster '305 does not disclose unthreading a guide element to remove it. The only method Foerster '305 discloses for separating the center wire (18) from the marker element (12) is to bring the marker element (12) into contact with the end of the tube (54), causing the center wire (18) to break from the marker element (12). Therefore, Foerster '305 does not anticipate claim 32 and claim 32 is patentable over Foerster '305.

Claim 42 is directly dependent on claim 30 and further requires the step of locating the area of interest in the tissue mass by following the guide element to the imaging element.

Foerster '305 does not disclose locating an area of interest in a tissue mass by following a guide element to an imaging element. The only method Foerster '305 discloses for locating the area of interest is to use state-of-the-art imaging systems to visualize the marker element (12). Therefore, Foerster '305 does not anticipate claim 42 and claim 42 is patentable over Foerster '305.

Claim 69 requires a delivery apparatus comprising an introducer defining a lumen with an expulsion opening, a piston slidably received within the lumen, and a medical device. The medical device comprises an imaging element and a guide element connected to the imaging element and having a separable portion. The expulsion opening is positioned within the tissue mass such that when the piston is advanced into a recess formed between a distal end of the piston and the expulsion opening, at least the imaging element is expelled through the expulsion opening into the tissue mass. When the expulsion opening is withdrawn from the tissue mass, the imaging element while still

connected to the guide element is placed within the tissue mass at an area of interest, and at least part of the guide element extends exteriorly of the tissue mass. After placement, when the separable portion is separated from the guide element, no part of the guide element extends exteriorly of the tissue mass.

Foerster '305 does not disclose a medical device comprising a guide element connected to an imaging element, where the guide element extends exteriorly of the tissue mass when the imaging element is expelled into the tissue mass. The deployment mechanism taught by Foerster '305 requires that the marker element (12) be brought into contact with the end of the tube (54), causing the marker element (12) to be anchored in the tissue mass and the center wire (18) to break from the marker element (12). Since deployment using the Foerster '305 marking instrument relies on tension to both anchor the marker element (12) and to break the connection between the marker element (12) and the center wire (18), it is necessary for the center wire (18) to be withdrawn in order to place the marker element (12). While a distal portion (18") of the center wire (18) may stay with the marker element (12) after it has been placed, this portion (18") is not said to or shown to extend exteriorly of the tissue mass.

Furthermore, Foerster '305 does not disclose a delivery apparatus comprising an introducer, a piston, and a medical device comprising an imaging element connected to a guide wire. Foerster '305 discloses a delivery apparatus comprising a tube (54b), a mandrel (98), and a marker element (12b). The marker element (12) is not connected to a guide wire. The mandrel (98) is used to deploy the marker element (12b) from the tube (54b) by compression. In another embodiment, Foerster '305 shows the marker element (12) connected to the center wire (18). However, a piston is not shown in this embodiment, and moreover could not be employed since tension is required to deploy the marker element (12).

Therefore, since Foerster '305 does not show a medical device comprising a guide element connected to an imaging element, where the guide element extends exteriorly of the tissue mass when the imaging element is expelled into the tissue mass, or a delivery apparatus comprising an introducer, a piston, and a medical device comprising an imaging element connected to a guide wire, Foerster '305 does not anticipate claim 69

and claim 69 is patentable over Foerster '305. Claims 44-58, 62, 63, 66, 67 and 70 are also patentable over Foerster '305 for at least the same reasons that claim 69 is patentable, based on their direct or indirect dependency on claim 69.

Claim 56 is directly dependent on claim 69 and further requires a holder mounted to a portion of the guide element exterior of the tissue mass to hold the position of the guide element relative to the tissue mass.

Foerster '305 does not disclose does not disclose a holder mounted to a portion of a guide element. The claimed holder is not equivalent to a cannula, as stated by the Examiner. The cannula described by Foerster '305 is used as a delivery apparatus for the marker element (12); as such, the marker element (12) and the center wire (18) are contained within the cannula prior to deployment. The cannula is not mounted to a portion of a guide element, as required by claim 17. Therefore, Foerster '305 does not anticipate claim 56 and claim 56 is patentable over Foerster '305.

Claim 58 is indirectly dependent on claim 69 and further requires a threaded coupling between the guide element and the imaging element to form a releasable connection between the two.

Foerster '305 does not disclose a threaded coupling between a guide element and an imaging element. The Examiner takes the position that a threaded coupling is shown in FIG. 10 of Foerster '305. FIG. 10 shows the marker element (12a) inserted through a loop at the end of the center wire (18a). This is not equivalent to a threaded coupling, as Applicants have applied the term. Applicants have applied the term to mean a connection having screw threads, specifically, cooperating male and female threads (¶ [0048]). Therefore, Foerster '305 does not anticipate claim 58 and claim 58 is patentable over Foerster '305.

Claim 67 is directly dependent on claim 69 and further requires that the imaging element be releasable to permit the repositioning of the imaging element in the tissue mass.

Foerster '305 does not disclose an imaging element that can be repositioned. Foerster '305 makes no provisions for releasing and repositioning the marker element (12) once it is placed in the tissue mass. In fact, in one embodiment of Foerster '305,

implantation of the marker element (12) is explicitly stated to be permanent (¶ [0048]). Therefore, Foerster '305 does not anticipate claim 67 and claim 67 is patentable over Foerster '305.

In view of the foregoing remarks and amendments, it is submitted that all of the claims are in condition for allowance. Early notification of allowability is respectfully requested.

Respectfully submitted,

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